



## Clinical Research- Pilot Study

**Comparison of the efficacy of diode laser assisted scaling and root planning with & without herbal adjunct - 'Irimedadi Taila' in chronic periodontitis patients: Randomized control trial – Pilot study.**

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### ABSTRACT:

**Purpose:** This study aims to determine and compare the changes in probing pocket depth, sulcular bleeding index, plaque index, gingival index, Periodontal Inflamed Surface Area (PISA) values following scaling and root planing using diode laser with and without the use of "Irimedadi Taila". **Methodology:** 8 Subjects with periodontitis were included in this split mouth parallel group randomized control trial. Teeth on the control side and contralateral test side were treated using Conventional Ultrasonic Scaling followed by Diode Laser Curettage at 940 nm. Patients were instructed to take 5 drops of *Irimedadi Taila* and massage the intended site. The clinical examiner was blinded to the assignment of quadrants and Clinical parameters were recorded at baseline, 4 weeks and 8 weeks. **Results:** 8 Quadrants were randomized to each group. At 8 weeks Post Op, Results indicated a significant reduction in sulcular bleeding index in the test group. Other parameters such as Plaque Index, Gingival Index, PISA improved in both the groups. No adverse events were reported and the *taila* was well tolerated. **Conclusion:** The finding of this preliminary study indicates that diode laser curettage along with the usage of *Irimedadi taila* is effective for treatment of chronic periodontitis when compared to diode laser curettage alone.

**KEYWORDS:** Diode Laser, Herbal oil, Chronic Periodontitis, NSPT.

**CTRI reg no.** [CTRI/2024/06/069459](#)

RECEIVED ON:

28-04-2025

REVISED ON:

25-07-2025, 05-08-2025

ACCEPTED ON:

04-09-2025

Access This Article Online:

Quick Response Code:



Website Link:

<https://jahm.co.in>

DOI Link:

<https://doi.org/10.70066/jahm.v13i8.1852>

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CITE THIS ARTICLE AS

Shirley Joshini Samvel, Deepak Moses Ravindran, Divya Kumar, K Dhanadivya, S Muthukumar, S K Balaji. Comparison of the efficacy of diode laser assisted scaling and root planning with & without herbal adjunct - 'Irimedadi Taila' in chronic periodontitis patients: Randomized control trial – Pilot study. *J of Ayurveda and Hol Med (JAHM)*. 2025;13(8):2-11



## 1. INTRODUCTION

### Background and Rationale:

Periodontitis is an irreversible and destructive disease affecting the periodontium. It poses a tremendous challenge in both dental practice and public health. Being one of the most common chronic inflammatory conditions occurring in human population globally, successful control of periodontitis is important for maintaining not only oral health but also the overall systemic well-being. Untreated periodontitis progresses and leads to loss of teeth and is also linked to other systemic diseases such as cardiovascular disease, diabetes, and respiratory infections. Due to this multifaceted nature of periodontitis, a variety of treatment methods have been established, and both non-surgical and surgical treatments have important roles to play in its treatment. [1] Non-surgical therapy forms the backbone of periodontal therapy, and scaling and root planning (SRP) is the foundation of the initial therapy. SRP is the careful elimination of plaque and calculus from the teeth, supragingival and subgingival root surfaces. This process hinders disease advancement, reduces inflammation in the periodontal tissues, and enhances periodontal health. By debriding the infected sites, SRP breaks up the bacterial biofilm that initiates and progresses periodontal disease, thereby establishing a healthier oral condition. When SRP is done thoroughly and accurately and is supplemented by adjunctive treatments, it can yield favorable results, especially in cases of mild to moderate periodontitis. [2, 3]

Conventional SRP is the "gold standard" and is the initial or first phase of periodontal treatment. This treatment

approach typically involves the use of ultrasonic scalers for scaling, which can effectively remove deposits above and below the gumline, as well as curettes for the debridement (cleaning out) of periodontal pockets. In addition to these mechanical tools, modern periodontal therapy sometimes employs adjunctive technologies to enhance outcomes. [4, 5] Diode lasers, for instance, have been used as a second approach to periodontal pocket debridement. Research has indicated that when diode laser curettage is employed as an adjunct to non-surgical SRP, there is a higher degree of reduction in periodontal parameters such as probing depth and inflammation compared to SRP alone. [6, 7, 8] This combination of treatments demonstrates an improvement in overall clinical outcomes, especially in patients with more advanced forms of periodontitis.

In clinical practice, various commercially available antibiotics and antiseptics are often employed as adjuncts to SRP with the intention of further improving gingival and periodontal health. These adjuncts attack periodontal pathogens, complementing mechanical debridement. A challenge in this is microbial resistance that reduces the effectiveness of antibiotics with time and restricts the effectiveness of treatment protocols for patients. This has led to the need for alternative adjuncts that may avoid this issue. [9, 10]

An increasing number of herbal products, such as gels, gum paints, and oils, have entered the market and are widely used for the treatment and management of gingivitis and periodontitis. Natural herbs such as cranberry, green tea, aloe vera, *ajwain*, *triphala*, turmeric, tulsi, marigold, and neem have been promising in clinical trials and shown effectiveness

against the deposition of plaque and consequent gingivitis. The herbs provide a welcome respite from conventional medications as they are mostly linked to few side effects. Also, most of these herbs have anti-inflammatory, antioxidant, and antimicrobial activities that make them ideal for oral health support. One of the lesser well-known but possibly useful herbal remedies for gingivitis and periodontitis is "Irimedadi taila". [10] This is an Ayurvedic oil that is commercially prepared and traditionally used for practices such as oil pulling or gargling, which are a part of Ayurvedic oral health routines. Preparations of *Irimedadi taila* is intricate and made from variety of medicinal drugs, such as *Irimeda twak* (*Vachellia farnesiana* (L.) Wight & Arn.), *Tilataila* (*Sesamum indicum* L.), *Kshrivrikshatwak* - Bark of 5 medicinal plants with Latex of *Nyagrodha* (*Ficus benghalensis* Linn.), *Udumbara* (*Ficus racemosa* Linn.), *Ashvattha* (*Ficus religiosa* L.), *Plaksha* (*Ficus Lacor* Buch-Ham.), *Parisha* (*Thespesia populnea* L.Sol.) , *Priyangu* (*Callicarpa macrophylla* Vahl.), *Dhataki* (*Woodfordia fruticosa* Kurz.), *Yashti*(*Glycyrrhiza glabra* L.), *Trijatha* (*Citrus aurantium* L.), *Manjishta* (*Rubia cordifolia* L.), *Sarala* (*Tephrosia purpurea* Pers.) , *Vaidedi* (*Crepe ginige*, *Alpinia galanga* L. Willd.), *Gayatri* (*Cleodendrum* sp.), *Jati* (*Jasminum grandiform* L.), *Katphala* (*Diospyros montana* Roxb.) , *Musta* (*Cyperus rotundus* L.), *Shvetachandana* (*Santalum album* L.), *Rakta Chandan* (*Pterocarpus santalinus* L.f.), *Mamsi* (*Pergularia daemia* Chiov.), *Karpoora*, *Mrinala* (*Cinnamomum camphora* J.Presl) , *Gairika* (*Red ochre or hematite*) , *Mishi* (*Foeniculum vulgare* Mill.), *Kumkuma*(*Crocus sativus* L.), *Padmakesara* (*Nelumbo nucifera* Gaertn.), *Samanga* (*Santalum album* L.), *Agaru* (*Aquilaria agallocha* Roxb.

Ex Colebr.), *Lodhra* (*Symplocos racemosa* Roxb.), *Takkola* (*Capparis zeylanica* L.), *Manjishta* (*Rubia cordifolia* L.), *Bilvapatra* (*Aegle marmelos* L. Corrêa), *Jaya* (*Oryza sativa* L.), *Brihati* (*Solanum indicum* Linn.), *Suradruma* (*Cedrus deodara* Roxb. ex D. Don), *Sprikka* (*Anisomeles malabarica* L.R.Br. ex Sims.), *Laksha* (*Laccider lacca kerr.*), *Shaileya* (*Pamelia perlata* Huds. Ach.), *Palasha* (*Butea monosperma* Lam.), *Rajani* (*Oroxylum indicum* Kurz.), *Daruharidha* (*Berberis aristata* DC.), *Tejani* (*Pterospermum acerifolium* Willd.) , *Pushkara* (*Inula racemosa* Hook.f. & Thomson), *Madana* (*Randia dumetorum* Lam.), *Pradhakaleya* (*Coscinium fenestratum* Gaertn. Colebr.), and *Vyaghri* (*Solanum xanthocarpum* Schras. & Wendl.). All these ingredients are handpicked based on their therapeutic potential and the process of preparation is a boil-down using "kashaya" (decoctions) and "kalka" (Ayurvedic medicinal pastes) prepared from herbal ingredients based on traditional Ayurvedic recipes. This process brings out the therapeutic potential of the ingredients, leading to highly active oil that can be used for oral health. [11, 12]

*Irimedadi Taila* is indicated in Ayurvedic therapy for an array of oral health disorders, such as aphthous ulcers, glossitis (tongue inflammation), gum hyperaemia, stomatitis, gingivitis, pyorrhea, removal of stains and prevention of dental caries. There has been little scientific evidence that directly examines the effectiveness of *Irimedadi taila* in treatment of gingivitis and periodontitis, despite its suspected properties. The properties of *Irimedadi Taila* is least explored on its therapeutic effects on laser assisted non-surgical periodontal therapy. Thus, the objective of this study

was to evaluate the clinical periodontitis, employing standard periodontal parameters for yielding objective, quantifiable results.

**Objectives:**

To clinically evaluate the efficacy of Diode Laser assisted SRP with and without herbal adjunct: "*Irimejadi Taila*" in Chronic Periodontitis patients in terms of periodontal parameters such as PPD, Gingival Index, Modified Sulcular bleeding index, Plaque Index, Periodontal Epithelial Surface Area (PESA) & Periodontal Inflamed Surface Area (PISA) scores recorded at baseline, 4 and 8 weeks.

**2. METHODOLOGY:**

Patients with Stage 2 Grade B periodontitis were recruited in the Outpatient section of Department of Periodontology. The patients were initially screened for the periodontal parameters such as PPD, Gingival Index, Modified Sulcular bleeding index, Plaque Index, Periodontal Epithelial Surface Area (PESA) & Periodontal Inflamed Surface Area (PISA). They were evaluated again at 4 and 8 weeks.

**Trail Design:**

This study is a Single Centre, Single Blinded, Split Mouth, Randomized Control Trial. Quadrants in each participants were individually randomized. Allocation ratio of 1:1 was followed.

The study was conducted in Outpatient section, Department of Periodontology, Sri Ramachandra Dental College and Hospital, Sri Ramachandra Institute of Higher Education and Research, Chennai, India.

**Eligibility Criteria:**

**Inclusion Criteria:**

Patients from age 30 - 60 years, both male and female, patients diagnosed with generalized chronic periodontitis with Periodontal Probing Depth (PPD) greater than 4 mm in more than one quadrant, patients who had not undergone oral prophylactic procedures for the past 6 months were included in this study.

**Exclusion Criteria:**

Patients on antibiotics / any other drugs for the past 3 months, Pregnant women / lactating mothers, patients with systemic diseases, Patients with deleterious habits such as tobacco/alcohol, patients with partial dentures, and overhanging restorations / orthodontic appliances were excluded in this study.

**Intervention and Comparator:**

After enrolment of patients based on Inclusion and Exclusion Criteria, Quadrants in patients with PPD > 4mm were randomly assigned into two different groups. The test quadrant and control quadrant were randomized post treatment procedure (i.e., SRP followed by Diode Laser Curettage) with the help of random number-generated software (Google random number generator between 1 & 2). "1" signified Test Group, "2" signified control group. Sample size was calculated based on a previous study by Fida A, Qureshi S, Mumtaz F. [10]

Group A: (n = 8) – Quadrant treated with Diode laser-assisted scaling and root planing and *Irimejadi taila* applied post-treatment

Group B: (n = 8) – Quadrant treated with Diode laser-assisted scaling and root planning only.

**Procedure and Intervention:**

Full mouth conventional scaling was done using an ultrasonic scaler. 2 weeks post oral prophylaxis; root

planning was done under local anesthesia using curettes in both the test and control quadrants followed by Diode laser curettage. Diode laser curettage was carried out using Biolase™ ezlase Diode Laser at 3 W Power setting, Continuous mode, 940 nm, 1 – 1.5J energy setting. The laser tip was passed along the pocket lining under local anesthesia in both the control and test quadrants.

Post-treatment, the randomized test and control quadrant is mentioned to the patient. For the test quadrant, the patients were instructed to take 4-5 drops of 'Irimedadi Taila' (Manufactured by Siddhayu Ayurvedic Research Foundation Pvt. Ltd., Batch no. W234930004) in their index finger and massage on their gums for 3-4 minutes, then rinse off with warm water. The control quadrant was not intervened with any additional procedure. The patients were instructed to perform the procedure in the test quadrant alone for 8 weeks and asked to report for follow up at 4<sup>th</sup> and 8<sup>th</sup> week.

### Reminder and Follow up :

Patients were reminded daily about the application of Taila on their respective test quadrants through the Medisafe© mobile application. Weekly follow up regarding the application of the medicine was done through phone call or text Messages.

### Outcome:

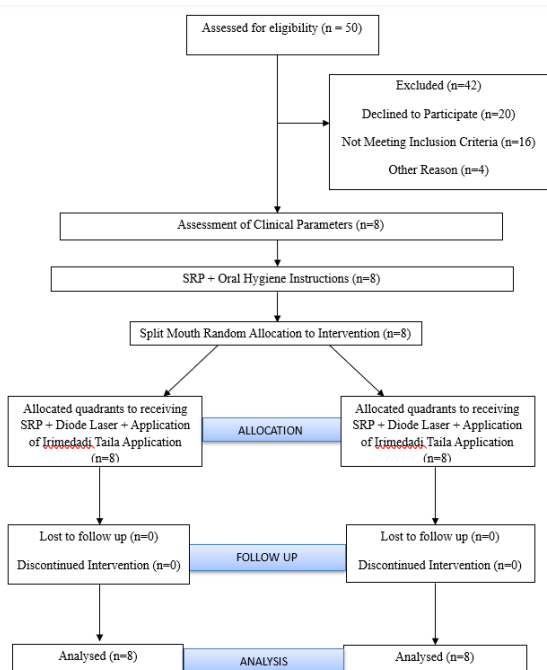
Before scaling and root planning, the patients' periodontal status was assessed using periodontal parameters such as probing pocket depth (PPD), sulcular bleeding index, plaque index, gingival index, and periodontal inflamed surface area (PISA) values. PPD was measured at 6 sites (Mesiobuccal , Mid-buccal , Distobuccal , Mesiolingual , Mid-lingual , Distolingual) per tooth using UNC probe. Modified sulcular bleeding index (Mombelli et al) was recorded for 6 mentioned sites for all teeth in the test and control quadrants using UNC Probe. Plaque Index (Silness and Loe et al) and Gingival Index (Loe and Silness et al) were recorded at all 6 sites for all the teeth in both test and control quadrants using mouth mirror and Shepherd's hook explorer. PISA was calculated using the formulated excel sheet for all the teeth in test and control quadrants. These parameters were assessed at 4<sup>th</sup> and 8<sup>th</sup> week recall visit.

### Harm:

No adverse effects were reported during the course of this trail.

### Sample size and sampling technique:

Sample size was estimated using A priori (t test) <sup>8</sup> and was found to be 16, with 5% level of significance , 95% power and allocation ratio of 1:1 ( with reference to key article A total of 8 patients were enrolled and 2



Flowchart 1: Consort Flow Chart

Quadrants were selected for each patient to be test and control groups. All patients reported for follow up.

**Randomization:**

After enrollment of patients based on Inclusion and Exclusion Criteria, Quadrants in patients with PPD > 4mm were randomly assigned into two different groups. The test quadrant and control quadrant were randomized post treatment procedure ( i.e., SRP followed by Diode Laser Curettage) with the help of random number-generated software (Google random number generator between 1 & 2 ). “1” signified Test Group, “2” signified control group. Simple randomization was followed.

Group A: (n = 8) – Quadrant treated with Diode laser-assisted scaling and root planing and Irimedadi applied post-treatment

Group B: (n = 8) – Quadrant treated with Diode laser-assisted scaling and root planing only.

**Allocation and Concealment mechanism:**

Random allocation sequence was generated using Google random number generator between 1 & 2 ). “1” signified Test Group, “2” signified control group. The allocation was concealed.

**Implementation:**

The principle investigator enrolled and assigned the quadrants according to random allocation sequence.

**Blinding:**

This is a single blinded RCT, where the clinician (examiner) was blinded about the test and control quadrants.

**Statistical Analysis:**

Data analysis was done by using 'IBM-SPSS-Statistics-20' software. The tables were generated using Microsoft Office Excel software. Intragroup comparison was done

using t test and Intergroup comparison was done using Mann Whitney U test.

**3. RESULTS:**

A total of 8 patients (16 Quadrants, 2 Quadrants for each patient) diagnosed with chronic periodontitis affecting more than one quadrant were enrolled, with 8 quadrants included each in Test and control group. The average age of participants was 39.75 years, with a standard deviation of 3.4 years. The study involved 4 males and 4 females. (Flowchart 1)

**Intragroup comparison:**

The intragroup comparison shows a faster pace of reduction in PPD from baseline through 4 and 8 weeks in the test group (Group 1) compared to the control group (Group 2). The Test group exhibited up to a 50% reduction in the Plaque Index and Gingival Index from baseline to 8 weeks, whereas the Control group showed only about a 20% difference. Additionally, the Test group demonstrated a statistically significant reduction in the Modified Sulcular Bleeding Index from baseline to 8 weeks compared to the Control group. PISA scores were noticeably reduced in the Test group throughout the timeline compared to the Control group. (Table 1)

**Table 1: Intragroup Comparison of PPD, Plaque Index, Gingival Index, Modified Sulcular Bleeding Index, PESA, and PISA scores at baseline, 4 weeks, and 8 weeks.**

PPD			
	Baseline	4 week	8 week
Group 1	4.64 ± 1.93	3.32 ± 0.86	3.07 ± 0.64
Group 2	3.72 ± 1.17	3.20 ± 0.71	2.82 ± 0.65
Plaque Index			
Group 1	1.31 ± 0.11	0.75 ± 0.09	0.592 ± 0.17
Group 2	1.24 ± 0.43	1.05 ± 0.25	0.90 ± 0.21

Gingival Index			
Group 1	1.05 ± 0.44	0.61 ± 0.21	0.52 ± 0.19
Group 2	1.04 ± 0.63	0.82 ± 0.51	0.90 ± 0.21
Modified Sulcular Bleeding Index			
Group 1	1.51 ± 0.48	0.57 ± 0.31	0.43 ± 0.24
Group 2	1.42 ± 0.41	0.95 ± 0.31	0.83 ± 0.35
PESA			
Group 1	678.81 ± 268.99	492.88 ± 218.95	397.22 ± 206.93
Group 2	615.06 ± 203.95	509.988 ± 192.208	462.71 ± 186.91
PISA			
Group 1	372.87 ± 201.61	230.62 ± 129.31	142.41 ± 74.941
Group 2	316.81 ± 146.91	237.8 ± 123.24	202.88 ± 123.46

Gingival Index	Group 1	0.53 ± 0.35	0.401
	Group 2	0.40 ± 0.47	
Modified Sulcular Bleeding Index	Group 1	1.08 ± 0.41	0.021
	Group 2	0.59 ± 0.26	
Pesa	Group 1	281.59 ± 106.35	0.021
	Group 2	152.35 ± 58.86	
Pisa	Group 1	230.46 ± 136.39	0.093
	Group 2	113.92 ± 103.66	



CONTROL QUADRANT PRE OPERATIVE TEST QUADRANT  
IMAGE 1 : BASELINE PREOPERATIVE



TEST QUADRANT CONTROL QUADRANT  
IMAGE 2 : CONVENTIONAL SRP FOLLOWED BY DIODE LASER CURETTAGE



IMAGE 3 : APPLICATION OF IRIMEDADI TAILA IN TEST QUADRANT POST BRUSHING



TEST QUADRANT CONTROL QUADRANT  
IMAGE 4 : 4 WEEKS POST OP



TEST QUADRANT CONTROL QUADRANT

### Intergroup comparison:

The intergroup comparison revealed a statistically significant reduction in the number of bleeding sites per tooth, the Modified Sulcular Bleeding Index, and PESA scores in the Test group compared to the Control group. (Table 2)

**Table 2: Intergroup Comparison of PPD, Plaque Index, Gingival index, Modified Sulcular bleeding index, PESA, and PISA scores from Baseline to 8 weeks:**

Baseline - 8 Weeks Post Op	Group	Mean	p Value
Ppd	Group 1	1.56 ± 1.44	0.401
	Group 2	0.89 ± 0.77	
No. Of Bleeding Sites	Group 1	2.21 ± 0.62	0.003
	Group 2	1.06 ± 0.50	
Plaque Index	Group 1	0.53 ± 0.20	0.248
	Group 2	0.34 ± 0.33	

#### 4. DISCUSSION:

Scaling and root planning is the cornerstone of periodontal non-surgical treatment and are core procedures for treating periodontitis. Diode laser-assisted SRP is a modern technique for the treatment of periodontal disease, using the precision and selectivity of lasers to improve treatment responses, as described in different literature. This method entails the application of a diode laser at a wavelength of approximately 810 to 980 nm as an adjunct to conventional mechanical instrumentation during periodontal pocket debridement. The laser energy interacts with pigmented bacterial cells, resulting in microbial killing and decontamination of the periodontal pocket environment. It has a few advantages over traditional SRP methods. [6] The minimal trauma of laser energy may reduce damage to the periodontal tissue, resulting in reduced postoperative discomfort and quicker healing time. It is notable, though, the diode laser-assisted SRP must be viewed as an adjunct or ancillary modality, not as a sole treatment for periodontal disease. [7]

In this study, we noticed a remarkable reduction in the Modified Sulcular Bleeding Index, number of bleeding sites per tooth, and Periodontal Epithelial Surface Area (PESA) scores in the quadrant treated with *Irimejadi taila*, reflecting its effectiveness in enhancing gingival health over diode laser-assisted scaling and root planing alone. No adverse effects were reported by the patients during the course of the study. In addition to a statistically significant decrease in the index scores, clinical improvement was observed with a shift from moderate to mild gingivitis. Hence, *Irimejadi taila* as an

adjunct reduces PESA and Modified sulcular bleeding index scores compared to Diode Laser-assisted scaling and root planing alone. These findings are consistent with previous research by Rao et al. [13] wherein *Irimejadi taila* improved the periodontal status in over 80% of the participants. In a study by Mali G V et al similar results were observed, this concluded that *Irimejadi taila* is as effective as chlorhexidine gluconate in preventing plaque accumulation and gingivitis when used along with mechanical plaque control. Research conducted by, Apsalli et.al., [14] Parwani et.al., Rahmani et al., and Deshmukh et al. [15] contrasting herbal mouthwashes to chlorhexidine mouthwash provided similar outcomes, proving to be effective in plaque and gingivitis prevention. It is also based on a study conducted by Shweta et al, where patients who used *Irimejadi taila* as an adjunct to routine SRP exhibited bleeding on probing and gingival index reduction. *Irimejadi taila* contains Clove (*Syzygium aromaticum*), Tila oil (*Sesamum indicum*), *Gayatri* (*Acacia catechu*), *Arimaedah* (*Acacia farnesiana*/Cassia flowers), and various other *Manjishtha* (*Rubia cordifolia*) ingredients. *Gayatri* Herb has been proven to possess astringent and bacterial properties, while *Manjishtha* is analgesic, anti-inflammatory agent, astringent and blood purifier. Clove is an anti-cariogenic, analgesic, and antimicrobial agent, and tila oil acts as an anti-plaque and anti-gingivitis agent. Benzaldehyde, methyl salicylate, and salicylic acid in Cassia oil are responsible for its astringent and demulcent actions, making it effective for healing gingival bleeding. [10] The improvement in gingival health in the test quadrant can be due to the ingredients contained in the *Irimejadi taila*. In addition,

physical stimulation of the gingiva through gingival massage with fingers promotes keratinization and enhances gingival blood supply, thus helps in the reduction of gingival inflammation and leads to better periodontal health. Nevertheless, more research is required to explain the precise mechanism of the activity of the constituents of *Irimejadi taila* on gingival health.

Feedback from the patients recorded the oil's bitter taste and pungent odor, which posed a challenge to its daily use post-brushing. Further development in research and study design should concentrate on improving the oil's taste and odor, thereby enhancing patient compliance for daily use. Possible future directions involve the incorporation of this *taila*'s ingredients into other formulations gels, suspensions, etc.

#### **Limitations:**

The limitations of the study are a small sample size, limited follow-up period and absence of microbiological testing to validate clinical findings. To overcome these limitations, future studies can be undertaken by performing longitudinal studies with larger sample sizes to assess the long-term implications of *Irimejadi taila*. Additional clinical trials are essential to investigate its antimicrobial activity against periodontal disease pathogens, its substantivity, Minimum Inhibitory Concentration (MIC), and its effect on overall systemic health.

#### **5. CONCLUSION:**

In the limits of this clinical trial, the results indicate that *Irimejadi taila* is effective for enhancing periodontal parameters when employed in addition to mechanical plaque control techniques. Furthermore, it provides a

natural alternative for those who want to avoid the possible side effects associated with alcohol-containing, chlorhexidine mouthwashes.

#### **Abbreviations:**

SRP – Scaling and Root Planning

PISA - Periodontal Inflamed Surface Area

PESA – Periodontal Epithelial Surface Area

PPD – Probing Pocket Depth

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Approval of final manuscript: All authors

**Conflict Of Interest** – The authors declare no conflicts of interest.

**Source of Support** – The authors declare no source of support.

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